

### § 37.41

### 42 CFR Ch. I (10–1–00 Edition)

(Form CDC/NIOSH (M) 2.8), and miner identification document.

(c) A roentgenographic examination shall be made in a facility approved in accordance with § 37.42 by or under the supervision of a physician who regularly makes chest roentgenograms and who has demonstrated ability to make chest roentgenograms of a quality to best ascertain the presence of pneumoconiosis.

#### § 37.41 Chest roentgenogram specifications.

(a) Every chest roentgenogram shall be a single posteroanterior projection at full inspiration on a film being no less than 14 by 17 inches and no greater than 16 by 17 inches. The film and cassette shall be capable of being positioned both vertically and horizontally so that the chest roentgenogram will include both apices and costophrenic angles. If a miner is too large to permit the above requirements, then the projection shall include both apices with minimum loss of the costophrenic angle.

(b) Miners shall be disrobed from the waist up at the time the roentgenogram is given. The facility shall provide a dressing area and for those miners who wish to use one, the facility shall provide a clean gown. Facilities shall be heated to a comfortable temperature.

(c) Roentgenograms shall be made only with a diagnostic X-ray machine having a rotating anode tube with a maximum of a 2 mm. source (focal spot).

(d) Except as provided in paragraph (e) of this section, roentgenograms shall be made with units having generators which comply with the following: (1) The generators of existing roentgenographic units acquired by the examining facility prior to July 27, 1973, shall have a minimum rating of 200 mA at 100 kVp.; (2) generators of units acquired subsequent to that date shall have a minimum rating of 300 mA at 125 kVp.

NOTE: A generator with a rating of 150 kVp. is recommended.

(e) Roentgenograms made with battery-powered mobile or portable equipment shall be made with units having a

minimum rating of 100 mA at 110 kVp. at 500 Hz, or of 200 mA at 110 kVp. at 60 Hz.

(f) Capacitor discharge and field emission units may be used if the model of such units is approved by ALOSH for quality, performance, and safety. ALOSH will consider such units for approval when listed by a facility seeking approval under § 37.42 of this subpart.

(g) Roentgenograms shall be given only with equipment having a beam-limiting device which does not cause large unexposed boundaries. The beam limiting device shall provide rectangular collimation and shall be of the type described in part F of the suggested State regulations for the control of radiation or (for beam limiting devices manufactured after August 1, 1974) of the type specified in 21 CFR 1020.31. The use of such a device shall be discernible from an examination of the roentgenogram.

(h) To insure high quality chest roentgenograms:

(1) The maximum exposure time shall not exceed  $\frac{1}{20}$  of a second except that with single phase units with a rating less than 300 mA at 125 kVp. and subjects with chests over 28 cm. posteroanterior, the exposure may be increased to not more than  $\frac{1}{10}$  of a second;

(2) The source or focal spot to film distance shall be at least 6 feet;

(3) Medium speed film and medium speed intensifying screens are recommended. However, any film-screen combination, the rated "speed" of which is at least 100 and does not exceed 300, which produces roentgenograms with spatial resolution, contrast, latitude and quantum mottle similar to those of systems designated as "medium speed" may be employed;

(4) Film-screen contact shall be maintained and verified at 6 month or shorter intervals;

(5) Intensifying screens shall be inspected at least once a month and cleaned when necessary by the method recommended by the manufacturer;

(6) All intensifying screens in a cassette shall be of the same type and made by the same manufacturer;

(7) When using over 90 kV., a suitable grid or other means of reducing scattered radiation shall be used;

(8) The geometry of the radiographic system shall insure that the central axis (ray) of the primary beam is perpendicular to the plane of the film surface and impinges on the center of the film;

(9) A formal quality assurance program shall be established at each facility.

(i) Radiographic processing:

(1) Either automatic or manual film processing is acceptable. A constant time-temperature technique shall be meticulously employed for manual processing.

(2) If mineral or other impurities in the processing water introduce difficulty in obtaining a high-quality roentgenogram, a suitable filter or purification system shall be used.

(j) Before the miner is advised that the examination is concluded, the roentgenogram shall be processed and inspected and accepted for quality by the physician, or if the physician is not available, acceptance may be made by the radiologic technologist. In a case of a substandard roentgenogram, another shall be immediately made. All substandard roentgenograms shall be clearly marked as rejected and promptly sent to ALOSH for disposal.

(k) An electric power supply shall be used which complies with the voltage, current, and regulation specified by the manufacturer of the machine.

(l) A densitometric test object may be required on each roentgenogram for an objective evaluation of film quality at the discretion of ALOSH.

(m) Each roentgenogram made hereunder shall be permanently and legibly marked with the name and address or ALOSH approval number of the facility at which it is made, the social security number of the miner, and the date of the roentgenogram. No other identifying markings shall be recorded on the roentgenogram.

[43 FR 33715, Aug. 1, 1978, as amended at 52 FR 7866, Mar. 13, 1987]

#### § 37.42 Approval of roentgenographic facilities.

(a) Approval of roentgenographic facilities given prior to January 1, 1976,

shall terminate upon August 1, 1978 unless each of the following conditions have been met:

(1) The facility must verify that it still meets the requirements set forth in the regulations for the second round of roentgenographic examinations (38 FR 20076) and it has not changed equipment since it was approved by NIOSH.

(2) From July 27, 1973, to January 1, 1976, the facility submitted to ALOSH at least 50 roentgenograms which were interpreted by one or more "B" readers not employed by the facility who found no more than 5 percent of all the roentgenograms unreadable.

(b) Other facilities will be eligible to participate in this program when they demonstrate their ability to make high quality diagnostic chest roentgenograms by submitting to ALOSH six or more sample chest roentgenograms made and processed at the applicant facility and which are of acceptable quality to the Panel of "B" readers. Applicants shall also submit a roentgenogram of a plastic step-wedge object (available on loan from ALOSH) which was made and processed at the same time with the same technique as the roentgenograms submitted and processed at the facility for which approval is sought. At least one chest roentgenogram and one test object roentgenogram shall have been made with each unit to be used hereunder. All roentgenograms shall have been made within 15 calendar days prior to submission and shall be marked to identify the facility where each roentgenogram was made, the X-ray machine used, and the date each was made. The chest roentgenograms will be returned and may be the same roentgenograms submitted pursuant to § 37.51.

NOTE: The plastic step-wedge object is described in an article by E. Dale Trout and John P. Kelley appearing in "The American Journal of Roentgenology, Radium Therapy and Nuclear Medicine," Vol. 117, No. 4, April 1973.

(c) Each roentgenographic facility submitting chest roentgenograms for approval under this section shall complete and include an X-ray facility document describing each X-ray unit to be used to make chest roentgenograms under the act. The form shall include:

(1) The date of the last radiation safety